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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,599	04/02/2007	Benjamin Guy Davis	7765P001	6198

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BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP  
1279 OAKMEAD PARKWAY  
SUNNYVALE, CA 94085-4040

EXAMINER
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KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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11/09/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,599	<b>Applicant(s)</b> DAVIS ET AL.	
	<b>Examiner</b> ANDREW D. KOSAR	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26,28,29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,24-26,28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/1/10</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Applicant's amendments and arguments filed August 26, 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 1-26, 28, 29, 31 and 32 are pending. Claims 1-22, 24-26, 28 and 29 remain withdrawn for the reasons of record. Claims 23, 31 and 32 have been examined on the merits.

Applicant has incorporated claim 30 into claim 23, thus overcoming the anticipation rejections.

With regards to the obviousness rejection, Applicant argues that the chemistry of Davis is  $\text{carb-S-SO}_2\text{Me} + \text{protein-SH} \rightarrow \text{protein-S-S-carb}$ , whereas the instant claims are  $\text{carb-S-Se-R} + \text{protein-SH} \rightarrow \text{protein-S-S-carb} + \text{R-SeH}$ . Applicant argues that the examiner has failed to demonstrate that S-SO<sub>2</sub> substituted with S-Se would have similar properties and lead to the same chemical products and that it is not obvious to substitute one for the other. Applicant further argues that there is nothing of record that suggests the Soret band would red shift relative to the peptide/protein bound form. Applicant further asserts that there is no motivation to combine the references and asserts that there is nothing that would suggest the reaction would be successful.

Respectfully, the examiner disagrees. The rejection is based upon the premise that Davis teaches the final product, the SBL-Glc, and that the artisan would look to the art for the most economical, efficient and simplest way to form the product. While Davis teaches the use of Carb-S-SO<sub>2</sub>Me, the artisan would have recognized that alternatives, such as thioglucose (Glc-SH, which is commercially available, as identified by Wong), could be employed in the method. The artisan, in looking to other related art- particularly the art of Engman and Hsieh, show the

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use of -SePh in the coupling of protein-S-S-R compounds, thus there is ample teaching in the art to lead one to the use of SePh in the coupling reaction in order to obtain the benefit of the using commercially available starting materials in order to improve the method of Davis. With regards to the Soret band shift, Engman clearly shows that in Figure 1 the Soret band for the free benzene-selenolate is red shifted significantly from the bound form, thus clearly providing an efficient spectroscopic handle for monitoring the coupling reaction that would be immediately apparent to the artisan, being a synthetic chemist. Furthermore, there is nothing of record to show this method has any unexpected results/advantages as indicia of non-obviousness. Thus, for these and the reasons of record, the rejection is maintained, as applied to the amended claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 23 and 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIS (B.G. Davis et al. Tetrahedron: Asymmetry (2000) 11, pages 245-262; IDS 4/5/07),

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ENGMAN (L. Engman et al. Tetrahedron (1994) 50(9), pages 2929-2938), HSEIH (H.S. Hsieh et al. Biochemistry (1975) 14(8), pages 1632-1636), and WONG (US Patent 5,759,823).

The instant claims are drawn generally to a method of modifying a peptide/protein/amino acid having a selenenylsulfide group via reacting with an organic compound comprising a thiol, with the specific compound being reacting GlcSH with SBL-S156-Se-Ph.

Engman teaches reacting glutathione, a thiol containing organic compound, with glutathione-Se-Ph (GSSePh), a peptide comprising at least one selenenylsulfide group, to form GSSG and releasing PhSeH (e.g. scheme 3, page 2931). GSSePh is formed via reaction of GSH and PhSeBr (e.g. scheme 2 page 2931). Hsieh teaches the reaction of GSSeH with GSH to form H<sub>2</sub>Se and GSSG (e.g. scheme 3, page 1635).

Davis teaches SBL S156 is useful for glycosylation as “S156 is a surface-exposed residue that permits the introduction of externally disposed glycans resembling those found naturally in glycoproteins.” (page 246). SBL is a serine protease (e.g. Abstract). Davis teaches a variety of

sugars attached to SBL, for example:



, with the 2<sup>nd</sup> structure being SBL-Glc (e.g. scheme 2, page 248).

Wong teaches “Thiosugar acceptor saccharides, such as thioglucose are available from commercial sources (Sigma Chemical Co., St. Louis, Mo.)” (column 19, lines 4-6).

The difference between the instant claims and the teachings of Davis, is that while Davis teaches the product SBL-Glc, it does not teach the specific position of the modification (e.g. C156), nor does it teach the use of the thioglucose (Glc-SH) or the selenenylphenyl modified compound. It would have been obvious at the time of the invention to have used SBL(C156) as

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the base compound, as it is a protein that "permits the introduction of externally-disposed glycans resembling those found naturally in glycoproteins." Furthermore, one would have used the selenenylphenyl as the product released, PhSeH, can be used as a spectroscopic means to follow the reaction to completion, as the Soret band of the benzene-selenolate is red shifted from that of the peptide/protein bound phenylselenenyl compound. Furthermore, the starting material-thiolglucose (Glc-SH), and other thiol sugars are commercially available, as opposed to the thiol sugar of Davis, which requires formation using an N-Ac halogenated sugar with NaSSO<sub>2</sub>CH<sub>3</sub> in ethanol at 90°C for one hour or in DMF at RT for 2 hours. Thus, the artisan would recognize the advantage of using a starting material that is commercially available that reacts readily to form the final product. Furthermore, one would recognize using commercially available starting materials would employ a different synthetic route than that of Davis, and in looking to the art, would understand that the cysteine would require a selenenylsulfide group for the reaction to occur.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-22, 24-26, 28 and 29 drawn to an invention nonelected without traverse in the reply filed on January 14, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654